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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,054	04/25/2005	Yoram Eshel	06727/0202271-US0	9850

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EXAMINER

LAMPRECHT, JOEL

ART UNIT	PAPER NUMBER
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3737

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

E

Office Action Summary

Application No.

10/520,054

Applicant(s)

ESHEL ET AL.

Examiner

Joel M. Lamprecht

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17,22,23 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17,22,23 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-17, 22, 23, and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 13, 16, 18-23, 99, and 199 of copending Application No. 10/021238. Although the conflicting claims are not identical, they are not patentably distinct from each other because they comprise the same scope of subject matter and perform the same function. The lysis of cellulite is inherently the same as the lysis of adipose tissue as referenced by the common definition (Cellulite is the dimpling formed by the protrusion of subcutaneous fat into the dermis creating an undulating dermal-subcutaneous fat junction adipose tissue). It would have

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been obvious to one having ordinary skill in the art at the time of the invention to have addressed the lysis of adipose tissue and the lysis of cellulite by means of ultrasonic energy as one-in-the same process.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. 5. Claims 1-8, 10, 22, 23, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Cribbs, et al (US 6071239). Cribbs discloses a method for lipolytic therapy using ultrasound energy in which fat cells, i.e. adipose tissue, is non-invasively destroyed (abstract). The HIFU is concentrated to kill cells lying in the focal zone (Col 2, Lines 18-21) so that it does not significantly damage cells outside the focal zone using an ultrasonic array on the skin surface that is focused on the target volume (Col 1, Lines 60-62). Both the gain and the intensity are dynamically changed, or modulated, by a microprocessor (Col 4, Lines 44-46 and Col 5, Lines 56). Imaging is used to "monitor tissue destruction during the lipolytic therapy" (Col 6, Lines 40-41). The focus may be varied by adjustment of the dimensions of the focal zones (Col 2, Lines 62-64) as well as the axial

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dimension of the focal zone (Col 2, Line 39). It is inherent in the fact that if the dimensions of the focal zones are changed, the volumes will change as well.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9, 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cribbs in view of Friedman, et al (US 6645162). Cribbs, as discussed above, discloses a method for lysing adipose tissue, however fails to explicitly disclose sensing cavitations at target volume and ultrasonic energy, as well as the frequency range and duty cycle used in modulation over time. Friedman also discloses using focused ultrasound to remove adipose cells within a subcutaneous tissue region. Friedman teaches that ultrasonic energy should be applied using a relatively low duty cycle, for example of about "twenty percent or less, preferably ten percent or less, and more preferably about one percent or less" (Col 3, Lines 5-8). Also, the frequency range used is between 0.25 and 30 megahertz (claim 2), which is between 250 KHZ and 30000 KHz. The transducer may also include detectors for sensing cavitations (abstract) occurring at the focal zone. This sensor may be a "cavitation strip detector", which is on the transducer, which is therefore detecting ultrasonic energy coupling to the external surface of the body. It would have been obvious to one of ordinary skill in the art

at the time of the invention to modify the disclosure of Cribbs with the teachings of the reference by Friedman and use the frequencies, duty cycle, and sensors disclosed, as the specific frequency range and duty cycles used were chosen specifically to reduce trauma to surrounding tissue, which is the goal of the method disclosed by Cribbs.

5. In addition, using a sensor to monitor cavitations would be advantageous for the same reason, as the device disclosed by Friedman "may minimize damage, such as that caused by... heating of neighboring tissues when unfocused ultrasound is indiscriminately introduced into a tissue region" (Col 2, Lines 53-56). Cribbs teaches all the method steps as set forth above. The apparatus concerning the structure of the lysing adipose tissue device are considered inherently taught by the disclosure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML 3/1/07

Handwritten:
JML
EBC, MANTIS MEMBER
SPE 3768